

## Advisory Circular

Administration

Subject: EMERGENCY MEDICAL Date: 5/9/03 AC No: 121-33A

EQUIPMENT Initiated by: AFS-220 Change:

#### 1. What is the purpose of this advisory circular (AC)?

This AC provides guidance about onboard emergency medical equipment, including Automated External Defibrillators (AEDs) and Emergency Medical Kits (EMKs). It is intended to guide air carrier operators when establishing protocols for emergency medical equipment. The Federal Aviation Administration (FAA) expects and anticipates some variation among the programs that air carriers establish for emergency medical equipment. (Also see AC 121-34A, Emergency Medical Equipment Training.)

#### 2. Does this AC supersede any existing ACs?

This AC cancels AC 121-33, Emergency Medical Equipment, dated August 14, 2002. It also relates to existing AC 120-44A, Air Carrier First Aid Programs (http://www.faa.gov/avr/afs/cabinsafety/acidx.cfm), which is also a good reference source.

#### 3. What FAA regulations does this AC cover?

Title 14 of the Code of Federal Regulations (14 CFR) part 121, subpart X; part 121, appendix A as amended, to be effective April 12, 2004. (Please note that the <u>Federal Register</u>, codified version, incorrectly lists the effective date as May 12, 2004.)

#### 4. Who should read this AC?

FAA aviation safety inspectors (cabin safety and operations), part 121 air carrier certificate holders, directors of operations, directors of safety, crewmembers, AED manufacturers and suppliers, EMK suppliers.

### 5. When are emergency medical equipment enhancements required and on what size of aircraft?

As of April 12, 2004, the FAA will require AEDs and enhanced EMKs on all airplanes of air carriers operating under part 121 with a maximum payload capacity of more than 7,500 pounds and with at least one flight attendant. Affected airplanes typically would have a capacity for 30 passengers or more requiring at least one flight attendant. Such airplanes may not be operated unless they are equipped with required emergency medical equipment, including EMKs and AEDs. EMKs and AEDs are "no-go" items and must be carried as indicated on the Minimum Equipment List.

### 6. What emergency medical equipment enhancements must operators carry as of April 12, 2004?

At least one approved AED, legally marketed in the United States in accordance with Food and Drug Administration (FDA) requirements.

At least one approved EMK enhanced with the following items. These enhancements were not previously required in the EMK originally mandated in 1986.

Part 121, appendix A, specifies that the following items must be carried in EMKs as of April 12, 2004; (modifications to appendix A are rendered in bold):

CONTENTS	QUANTITY
Sphygmomanometer	1
Stethoscope	1
Airways, oropharyngeal (3 sizes): 1 pediatric, 1 small adult, 1 large adult or equivalent	3
Self-inflating manual resuscitation device with 3 masks (1 pediatric, 1 small adult, 1 large adult or equivalent)	1: 3 masks
CPR mask (3 sizes), 1 pediatric, 1 small adult, 1 large adult, or equivalent	3
IV Admin Set: Tubing w/ 2 Y connectors	1
Alcohol sponges	2
Adhesive tape, 1-inch standard roll adhesive	1
Tape scissors	1 pair
Tourniquet	1
Saline solution, 500 cc	1
Protective nonpermeable gloves or equivalent <sup>1</sup>	1 pair
Needles (2-18 ga., 2-20 ga., 2-22 ga., or sizes necessary to administer required medications)	6
Syringes (1-5 cc, 2-10 cc, or sizes necessary to administer required medications)	4
Analgesic, non-narcotic, tablets, 325 mg	4
Antihistamine tablets, 25 mg	4
Antihistamine injectable, 50 mg, (single dose ampule or equivalent)	2
Atropine, 0.5 mg, 5 cc (single dose ampule or equivalent)	2
Aspirin tablets, 325 mg	4
Bronchodilator, inhaled (metered dose inhaler or equivalent)	1
Dextrose, 50%/50 cc injectable, (single dose ampule or equivalent)	1
Epinephrine 1:1000, 1 cc, injectable, (single dose ampule or equivalent)	2
Epinephrine 1:10,000, 2 cc, injectable, (single dose ampule or equivalent)	2
Lidocaine, 5 cc, 20 mg/ml, injectable (single dose ampule or equivalent)	2
Nitroglycerine tablets, 0.4 mg	10
Basic instructions for use of the drugs in the kit	1

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<sup>&</sup>lt;sup>1</sup> Although the FAA requires only one pair of protective gloves, it recommends that operators keep additional pairs accessible on the aircraft. This would allow crewmembers to access a pair of gloves without having to locate and open an EMK.

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#### 7. What purpose do the enhanced items add to an EMK?

• *Non-narcotic analgesic tablets:* a general oral medication used mainly to relieve muscle aches and headaches

- *Oral antihistamine:* medication used mainly to relieve symptoms associated with allergies and hay fever
- Aspirin: a general oral medication used mainly to alleviate head and muscle aches and chest pain or heart attack
- *Atropine:* medication used mainly to increase heart rate, that may be needed to assist a passenger with an unstable cardiac rhythm
- Bronchodilator inhaler: a preparation of medication used to help restore normal breathing in asthmatics
- Epinephrine 1:10,000: medication used mainly for cardiac resuscitation
- *Lidocaine:* medication used mainly in cases of unresponsiveness to defibrillation and possibly for maintenance of normal heart rhythm after successful defibrillation
- An IV administration set including tubing with 2Y connectors (and, for placing the IV, alcohol sponges, tape, bandage scissors, and a tourniquet): equipment used for administering IV drugs (e.g., atropine, lidocaine, epinephrine) that may be needed to sustain heart function
- A self-inflating manual resuscitation bag (AMBU bag) (with 3 masks: 1 pediatric, 1 small adult, and 1 large adult): equipment that may be needed for continuation of respiratory support
- *CPR mask (1 pediatric, 1 small adult, 1 large adult)*: equipment that may be needed to protect a person while administering CPR

#### 8. What does "or equivalent" mean?

The FAA recommends that operators carry the required EMK items without substitution. The FAA has used the words "or equivalent" in part 121, appendix A, since 1986 (and will continue to use the words) to allow for any nomenclature or other changes the medical community might choose to make over the course of the lifetime of the regulation. The FAA references only generic terms under part 121, appendix A as amended. If you have a question about whether a certain medication or piece of equipment you choose to stock will meet the requirement, please contact the FAA Office of Aerospace Medicine.

Suppliers have asked the FAA whether diphenhydramine HCl injection is an acceptable equivalent to meet the requirement for antihistamine injectable. It is acceptable. They also have asked whether it is acceptable to stock universal masks where CPR masks or masks for resuscitation are required. In both situations, universal masks designed for the required sizes are acceptable as long as they meet the quantity requirements. In addition, some masks may be used to administer CPR and also may be used with the self-inflating manual resuscitation device. These masks often use a one-way valve, to protect the rescuer during CPR, and a separate connector for the resuscitation device. If the universal masks included in the EMK provide a means of administering CPR and also may be used with the self-inflating manual resuscitation

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device, then they are considered to be acceptable under both mask requirements. Therefore, a total of only three masks would be required.

#### 9. What does "approved" EMK and "approved" AED mean?

Approved EMK means that the FAA Principal Operations Inspector assigned to the holder of an operating certificate exercises approval for the Administrator, as appropriate, of equipment to be carried aboard a certificate holder's aircraft.

Approved AED means that it is legally marketed in the United States in accordance with FDA requirements. AEDs used on airplanes must be approved by the FDA for medical use and must conform to FDA standards. The FAA requires the power source (e.g., batteries) used to power AEDs to comply with all requirements in applicable Flight Standards Information Bulletins for Airworthiness, such as FSAW 98-05, Medical Portable Electronic Devices (PED) (http://www.faa.gov/avr/afs/cabinsafety/fsawidx.cfm), and in applicable FAA Technical Standard Orders (TSO), such as TSO-C142, Lithium Batteries (http://av-info.faa.gov/tso/tsocur/current.htm).

### 10. How can an operator comply with part 121, appendix A, at all times after an EMK and/or an AED is used during flight?

The regulation specifies "at least one" EMK and "at least one" AED as the minimum required on every flight for full compliance with part 121, appendix A. In the event that certain contents of an EMK are used during a flight, an inventory of the remaining contents and restocking of the contents would be needed to ensure that the minimum content requirements are met prior to any subsequent flight. For the sake of convenience, and to avoid delays, an airline may decide to overstock certain EMK items (in particular protective gloves and CPR masks), carry two EMKs, or establish a procedure for effecting one-for-one replacements as necessary.

The FAA acknowledges that there may be circumstances that would warrant a flight attendant needing only protective gloves, a CPR mask, or both from the EMK. Accessing an EMK for the purpose of retrieving one or both of these items could be problematic. Therefore, the FAA recommends that operators carry a few pairs of extra protective gloves and an extra CPR mask outside of the EMK.

The issue of AED replacement will not be as critical as with EMKs unless, for example, air carrier operators allow AEDs to be taken off their aircraft for continued assistance of a passenger during emergency ground transport. Individual airlines should develop a protocol for AED use, post-resuscitation guidelines, and any AED serviceability needs. At a minimum, before any subsequent flights, the AED must be "operative" and there must be at least one set of unused pads with the AED. AEDs usually are packaged with a spare battery and a spare set of pads. Operators may want to carry extra AED pads.

#### 11. Who is allowed to use the equipment?

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Flight attendants should grant access to the equipment only to trained crewmembers or to other persons qualified and trained in the use of emergency medical equipment. The decision to allow passengers to assist another passenger and have access to medical equipment is up to the air carrier and its agents. The FAA does not attempt to define the various medical specialties under part 121 because it limits access to the extent that the only person available to assist on a flight might not be included. It would be preferable for flight attendants to check the credentials of passengers holding themselves out as medical specialists.

It is unrealistic to expect flight attendants to achieve the same level of proficiency as emergency medical personnel who perform medical procedures on a routine basis. Flight attendants should not be expected to administer medications or to start IVs. If a critical in-flight medical event occurs and a passenger medical specialist is not available, it is recommended that the sick passenger be made as comfortable as possible and the pilot in command should determine whether to attempt safe diversion of the aircraft.

As stated in the rule, the decision to offer treatment or take other action (including safe diversion of the aircraft) is discretionary with the air carrier and its agents. The FAA does not require any actions by the air carrier and its agents and/or other passengers other than having certain emergency medical equipment on board the aircraft.

#### 12. What does "readily accessible" mean under § 121.803 effective April 12, 2004?

The FAA maintains use of the term "readily accessible" to conform § 121.803 to the same, long-standing terminology used for all emergency equipment under § 121.309 (b)(2). "Readily accessible" means, as it always has, that operators should place it where crewmembers can access the equipment quickly. To be sure, "readily accessible" is not intended to mean that the emergency medical equipment should be located where it might be subject to unauthorized access.

#### 13. Where should we store this equipment?

Because of the various configurations of aircraft required to carry enhanced emergency medical equipment, the FAA does not set one standard for storing the equipment. Airlines typically put the equipment in a locked compartment in an overhead, in a locked compartment attached to the bulkhead behind the last row of seats or in first class, or in an unlocked pouch attached to a bulkhead behind the last row of seats. All of these methods are acceptable. To avoid unnecessary distraction on the flight deck, and to ensure flight deck integrity, do not store AEDs in flight deck compartments.

#### 14. How must we inspect the equipment?

You must regularly inspect emergency medical equipment in accordance with inspection periods established in your operations specifications and maintain it according to manufacturers'

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specification. You should follow the manufacturer's recommended procedures regarding an AED self-check.

Flight attendants perform a routine preflight inspection of all emergency medical equipment in accordance with their air carrier's procedure to assure that it is on board the aircraft, secured, and ready if needed for use. Since EMKs are sealed, it's difficult to do a comprehensive visual inspection to ascertain that no EMK items are missing or unusable; therefore, it is critical to assure EMK integrity prior to the preflight inspection stage. Any discrepancies must be resolved in accordance with your air carrier's procedures.

#### 15. How often should we replace the EMK items?

The medications that must be carried in all EMKs as of April 12, 2004, have an expiration date of approximately 1 year: atropine, bronchodilator inhaler, dextrose, epinephrine, saline solution, and lidocaine; aspirin, non-narcotic analgesic, antihistamine, and nitroglycerine tablets. If temperature extremes occur on the aircraft at any time or if the medications have surpassed their expiration date then you should replace them. The FAA has not found expiration of medications to be problematic for air carriers under the existing requirement to carry injectable antihistamine, dextrose, epinephrine, and nitroglycerin tablets. Therefore, it does not anticipate that replacing medications would become problematic by requiring additional medications of similar shelf-life. The best practice, under normal circumstances, is to replace all of the medications annually.

#### 16. What does "damaging temperatures" mean under part 121, appendix A?

"Damaging temperatures" means temperature extremes which could alter the effectiveness of the emergency medical equipment.

Current manufacturer's specifications indicate that medications required for the EMK stored at controlled room temperature should remain stable within a temperature range of 59 to 86 degrees Fahrenheit (15 to 30 degrees Celsius). Medications carried in emergency medical vehicles, such as ambulances, reportedly remain stable within an even wider temperature range. The EMK and the aircraft cabin provide some protection from potentially harmful external temperatures. The aircraft cabin environment does not appear to negatively affect the required medications as long as they are replaced before their expiration date.

If an aircraft has been exposed to extremes of hot or cold temperatures, the medications in a liquid form (injectable) should be inspected before use. If they are yellow or cloudy, then they may have lost their effectiveness and should not be used. In general, once injectable medications are frozen they should not be used, and high, prolonged heat will degrade the efficacy of most medications.

In addition, the AED, batteries and defibrillator pads usually have a recommended temperature range for storage and operation. These temperature ranges vary between manufacturers, but are generally much wider than for the medications. The manufacturer's specifications should be consulted for proper handling procedures if the aircraft cabin exceeds the recommended

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temperatures. Prolonged exposure to temperatures outside the recommended limits may damage the batteries or may cause the pads to not adhere properly.

If an aircraft is parked or taken out of service for an extended period of time in a location where it may be exposed to temperature extremes, then the emergency medical equipment should be taken off the aircraft and protected.

# 17. Since some air carrier operators carry EMKs that may contain controlled substances, how can they be transported legally? Is transporting these substances compatible with Drug Enforcement Administration (DEA) regulation?

Although the FAA does not require any controlled substances for the EMK, some air carriers may purchase commercial EMKs that are prepackaged with a controlled substance(s) (for example, diazepam). Such EMKs cannot be purchased (or carried) unless a current DEA Registration Certificate is on file with the EMK distributor. If a controlled substance is compromised (e.g., lost, stolen, or missing) the operator must report it to the DEA.

#### 18. Does the FAA regulate safety standards for AEDs?

No. The FDA is responsible for regulating safety standards for the manufacture and use of AEDs. The FAA is responsible for regulating the safety of the power sources used in AEDs when carried on board a passenger-carrying aircraft. You should direct any questions about AEDs directly to the manufacturer and/or to the FDA Center for Devices and Radiological Health. AED manufacturers may have resources available to provide the FDA-required oversight.

For safety purposes, the FAA asks that certificate holders comply with the guidance in applicable Flight Standards Information Bulletins for Airworthiness, such as FSAW 98-05, Medical Portable Electronic Devices (PED). Certificate holders must also comply with the requirements of applicable TSOs such as TSO-C142, Lithium Batteries. The devices should be maintained in accordance with manufacturer's specifications and should be inspected in accordance with schedules developed under operations specifications. Currently, AEDs are powered by primary (not rechargeable) lithium batteries. Safety of these batteries is stressed because extremely energetic materials are used in lithium cells and they are not intrinsically safe. Safety concerns include the possibility of fire, explosion, and the venting of toxic or flammable gases.

#### 19. Are AED batteries that are not TSO'd under C-142 acceptable?

The FAA recommends that new AEDs powered by lithium batteries comply with TSO-C142. AEDs powered by batteries approved under TSO-C97, Lithium Sulfur Dioxide Batteries, currently placed on aircraft may continue to use these earlier approved batteries until replacement when they will be required to be approved under TSO-C142.

The FAA issued TSO-C142 on April 4, 2000. This TSO prescribes the minimum FAA performance standard that lithium cells and batteries must meet to be identified with the

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applicable TSO marking. The standards of this TSO apply to lithium cells and batteries intended to provide power for aircraft equipment including emergency and standby systems.

#### 20. Is labeling an AED with the statement "approved for use on aircraft" appropriate?

No. Arbitrary use of the statement "approved for use on aircraft" is not appropriate. It could lead to a safety problem because toxic gas venting precautions are required before placing AEDs containing lithium sulfur dioxide batteries in an airplane cabin. The battery manufacturer must supply a note with the batteries, reference paragraph 5.a.(1) of TSO-C142, that addresses installation procedures and limitations. If there is no compliance with "Toxic Gas Venting Precautions" in Appendix 1 of TSO-C142, it could present a safety problem. Marking requirements for lithium batteries is defined in 14 CFR part 21, § 21.607(d), and TSO-C142.

#### 21. What prompted requirements for emergency medical equipment enhancements?

The Aviation Medical Assistance Act (the Act) of 1998 [Pub. L. 105-170, 49 U.S.C. 44701] directed the FAA to determine whether current minimum requirements for air carrier emergency medical equipment and air carrier crewmember emergency medical training should be modified. As directed in the Act, the FAA conducted a year-long data collection on death or near-death inflight medical events. It revealed 188 total events resulting in 108 deaths (119 of these 188 total incidents were cardiac-related resulting in 64 deaths). For cardiac-related events on the aircraft, an AED was reported as "not available" for 40 events. An AED was available and used to deliver at least one shock in 17 separate events. From these events, four passengers were reported as having survived. Subsequent to the data collection, further investigation revealed that more passengers, and a flight crewmember, had also survived after having been shocked with an AED. Based on these events, it was determined that part 121 should be amended to require emergency medical enhancements, including enhanced training, enhanced EMKs, and AEDs.

/s/ James J. Ballough Director, Flight Standards Service

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